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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,554	01/18/2001	Patrick M. Alliel	200936USPCT	1650

22850 7590 08/05/2002

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EXAMINER
BROWN, STACY S

ART UNIT	PAPER NUMBER
1648	10

DATE MAILED: 08/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/719,554	ALLIEL ET AL.	
	Examiner	Art Unit	
	Stacy S Brown	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-37* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Group Art Unit 1648.**

2. Applicant's preliminary amendment, received July 15, 2002, is acknowledged and entered. Claims 1-37 are pending.

Election/Restrictions

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- Group I, claims 1 and 33, drawn to a nucleic acid fragment and vector comprising SEQ ID NO: 1 (*env*).
- Group II, claim 2, drawn to a nucleic acid fragment comprising SEQ ID NOS: 1 and 2 (*env* and *gag*).
- Group III, claim 3, drawn to a nucleic acid fragment comprising SEQ ID NOS: 1, 3-22, 28 and 61 (*env* and unknown). If Applicant intended to claim SEQ ID NO: 1 and one of SEQ ID NOS: 3-22, 28 and 61, then SEQ ID NO: 1 will be searched along with **one elected sequence** from SEQ ID NOS: 3-22, 28 and 61.
- Group IV, claim 4, drawn to transcripts generated from nucleic acid.

- Group V, claims 5-9, drawn to a diagnostic reagent having retroviral motifs comprising SEQ ID NO: 1-22, 28, 37-57, 59-61 and 121-122. Applicant must **elect one sequence** for examination.
- Group VI, claims 10 and 12, drawn to a method for detection of nucleic sequences of *env*. Applicant must **elect one sequence** for examination.
- Group VII, claim 11, drawn to a method for detection of nucleic sequences of *env* and *gag*. Applicant must **elect one sequence** for examination.
- Group VIII, claim 13, drawn to chimeric sequences.
- Group IX, claims 14-16, drawn to a method for detection/evaluation of overexpression/underexpression/modification of an HERV-7q type sequence. Applicant must **elect one sequence** for examination.
- Group X, claims 17-18, drawn to a kit for detecting autoimmune disease. Applicant must **elect one sequence** for examination.
- Group XI, claim 19, drawn to translational products.
- Group XII, claims 20-26 and 34, drawn to a peptide. Applicant must **elect one nucleic acid sequence and one amino acid sequence** for examination.
- Group XIII, claims 27 and 28, drawn to an antibody. Applicant must **elect one amino acid sequence** for examination.
- Group XIV, claim 29, drawn to a method for differential immunological screening of retroviral sequences. Applicant must **elect one amino acid sequence** for examination.

- Group XV, claim 30, drawn to a method for identification of endogenous retroviral motifs associated with cancer or neuropathological conditions. Applicant must elect either cancer or neuropathological conditions.
- Group XVI, claim 31, drawn to an application of the SEQ ID NO: 1 for the detection, prognosis and evaluation of genetic susceptibility to cancer, autoimmune and/or neurological components. Applicant must elect either cancer or neurological disease. (Autoimmune disease will be grouped with neurological disease.)
- Group XVII, claim 32, drawn to hybrid nucleic acid sequences.
- Group XVIII, claims 35-36, drawn to a gene therapy vector comprising SEQ ID NO: 1. Applicant must **elect one sequence** for examination.
- Group XIX, claim 37, drawn to transgenic animals. Applicant must **elect one sequence** for examination.

The inventions listed as Groups I-XXI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Claim 1, Group I, is drawn to a nucleic acid fragment comprising SEQ ID NO: 1. This sequence was known at the time of Applicant's invention, see attachment. Therefore, since Group I is anticipated by the prior art, there is no special technical feature linking the groups of inventions together.

The inventions are distinct, each from the other because of the following reasons:

a) Restriction between sequences is required in Groups III, V-VII, IX, X, XII-XIV, XVIII and XIX. The nucleic acid sequences are distinct from each other because they have different

lengths, nucleic acids, and encode different products. The amino acids are distinct from each other because they have different lengths and structures.

b) Groups I-V, VIII, X-XIII and XVI-XIX are all distinct products drawn to different nucleic acids, transcripts generated from the nucleic acids, diagnostics having different sequences, kits for detecting autoimmune disease, translational products, peptides encoded by the nucleic acids, immunogenic compositions and vaccines, antibodies, and transgenic animals. Groups I-III are distinct because they have different nucleic acid sequences encoding different products. The nucleic acids and amino acids/peptides are distinct products because they have different structures and functions. The peptides and antibodies are distinct because they have different structures, functions, modes of operation and effect. The gene therapy vector is distinct from the other nucleic acids because it comprises different sequences. The transgenic animals are distinct from the nucleic acids, proteins, peptides and antibodies because they are not disclosed as capable of use together. In summary, the products claimed do not share the same functions, structures, modes of operation and effects, and are therefore distinct products that are not disclosed as capable of use together.

c) Inventions (I-IV, X-XII and XVI-XIX) and (VI-VII, IX and XIV-XV) are unrelated. The nucleic acids, transcripts, kit for detecting autoimmune disease, translational products, peptide, hybrid nucleic acid sequences, vector and transgenic animals are not required to practice the methods of detecting nucleic acids, screening retroviral sequences or identifying retroviral motifs.

d) Inventions V and (VI-VII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using

the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product, comprising nucleic acids, can be used in a materially different method of using, such as inducing an immune response.

e) Inventions V and (IX, XIV and XV) are unrelated. The diagnostic reagent of Group V is not required to practice the methods of detecting sequences, screening sequences or identifying motifs.

f) Inventions VI and VII are distinct inventions because they require different sequences to practice the method, resulting in a different mode of operation, function and effect.

g) Inventions (VI-VII) and (VIII, IX and XVIII-XV) are unrelated inventions. The method of detecting nucleic acid sequences is not required to practice the other methods claimed. They have different method steps, reagents and functions.

h) Inventions VIII and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the chimeric sequences can be used in a materially different method of using such as inducing an immune response.

i) Inventions (VIII-XII) and (XIV-XV) are unrelated inventions. The chimeric sequences, translational products, peptides, kits for detecting autoimmune disease and method for detecting sequences are not required to practice the methods of Groups XIV and XV.

j) Inventions XIII and (XIV and XV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies can be used in a materially different process of using, such as inducing an immune response.

k) Inventions XIV and XV are distinct methods having different method steps, modes of operation, function and effect. The methods are not disclosed as capable of use together.

l) Restriction between cancer and neurological disease is required because the diseases are unrelated and would require further searching. Methods or products for detecting cancer and neurological diseases encompass different searches that are not co-extensive.

Because these inventions are distinct for the reasons given above and the sequence search and literature search required for one group is not required or not co-extensive for any other group, and therefore burdensome, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy S. Brown, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday and alternate Wednesdays from 6:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Stacy S. Brown
August 2, 2002

HANKYEL T. PARK, PH.D
PRIMARY EXAMINER

```
RESULT   4
HSAC000064
LOCUS       HSAC000064             56093 bp    DNA     linear   PRI 13-NOV-1996
DEFINITION  Human BAC clone RG083M05 from 7q21-7q22, complete sequence.
ACCESSION   AC000064
VERSION     AC000064.1  GI:1669369
KEYWORDS    HTG.
SOURCE      human.
  ORGANISM  Homo sapiens
            Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
            Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.
REFERENCE   1  (bases 1 to 56093)
  AUTHORS   Pauley,A.
  TITLE     The sequence of H. sapiens BAC clone RG083M05
  JOURNAL   Unpublished (1996)
REFERENCE   2  (bases 1 to 56093)
  AUTHORS   Waterston,R.
  TITLE     Direct Submission
  JOURNAL   Submitted (13-NOV-1996)
COMMENT     Genome Sequencing Center
               Department of Genetics, Washington University
               St. Louis, MO 63108, USA
               e-mail: sapiens@watson.wustl.edu

            NOTICE:  This sequence may not represent the entire insert of this
            clone.  It may be shorter because we only sequence overlapping
            sections once, or longer because we provide a small overlap between
            neighboring submissions.

            This sequence was finished as follows unless otherwise noted:
            all regions were double stranded or sequenced with an alternate
            chemistry; an attempt was made to resolve all sequencing problems,
            such as compressions and repeats; all regions were covered by
            sequence from more than one subclone; and the assembly was
            confirmed by restriction digest.

            SOURCE INFORMATION:
            This clone is from the first release of the human BAC library.  The
            library contains cloned DNA from a human male fibroblast cell line
            978SK.  For references see:  Shizuya et al., Proc. Natl. Acad. Sci.
            89:8794-8797 (1992); Kim et al., Genomics 34:213-218 (1996).
            VECTOR:  pBELO
            Selection:  chloramphenicol

            NEIGHBORING SEQUENCE INFORMATION:
            The orientation of this clone is unknown.  Actual start of this
            clone is at base position 1 of H_RG083M05; actual end is at 56093
            of H_RG083M05

            This clone contains STS sWSS1725.
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Qy    604 attacaaggaacctatccctgagaagagggaaaagaactattccacccttgtgacatggt 663
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db  35554 ATTACAAGGAACCTATCCCTGAGAAGAGGGAAAAGAACTATTCCACCCTTGTGACATGGT 35613

Qy    664 attagtcaagtcccttccctctaattcccccatccctagatacatcctgggaaggacccta 723
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db  35614 ATTAGTCAAGTCCCTTCCCTCTAATTCCCCATCCCTAGATACATCCTGGGAAGGACCCTA 35673

Qy    724 cccagtcatttttatctaccccaactgcggttaaagtggctggagtggagtcttggataca 783
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db  35674 CCCAGTCATTTTATCTACCCCAACTGCGGTTAAAGTGGCTGGAGTGGAGTCTTGGATACA 35733

Qy    784 tcacacttgagtcaaatcctggatactgccaaaggaacctgaaaatccaggagacaacgc 843
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Db  35734 TCACACTTGAGTCAAATCCTGGATACTGCCAAAGGAACCTGAAAATCCAGGAGACAACGC 35793

Qy    844 tagctattcctgtgaacctctagaggatttgcgcctgctcttcaaacaacaaccaggagg 903
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Db  35794 TAGCTATTCCTGTGAACCTCTAGAGGATTTGCGCCTGCTCTTCAAACAACAACCAGGAGG 35853

Qy    904 aaagtaactaaaatcataaatccccatggccctcccttatcatatttttctctttactgt 963
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Db  35854 AAAGTAACTAAAATCATAAATCCCCATGGCCCTCCCTTATCATATTTTTCTCTTTACTGT 35913

Qy    964 tcttttaccctctttcactctcactgcacccccctccatgccgctgtatgaccagtagctc 1023
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Qy   1024 cccttaccaagagtttctatggagaatgcagcgtcccggaaatattgatgccccatcgta 1083
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Db  35974 CCCTTACCAAGAGTTTCTATGGAGAATGCAGCGTCCCGGAAATATTGATGCCCCATCGTA 36033
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Qy    1084 taggagtctttctaagggaaccccccaccttcactgcccacacccatatgccccgcaactg 1143
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Db   36034 TAGGAGTCTTTCTAAGGGAACCCCCACCTTCACTGCCCACACCCATATGCCCCGCAACTG 36093

Qy    1144 ctatcactctgccactctttgcatgcatgcaaatactcattattggacaggaaaaatgat 1203
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Qy    1204 taatcctagttgtcctggaggacttggagtcactgtctgttggacttacttcacccaaac 1263
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Qy    1264 tggtatgtctgatgggggtggagttcaagatcaggcaagagaaaaacatgtaaaagaagt 1323
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Qy    1324 aatctcccaactcacccgggtacatggcacctctagcccctacaaaggactagatctctc 1383
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Db   36274 AATCTCCCAACTCACCCGGGTACATGGCACCTCTAGCCCCTACAAAGGACTAGATCTCTC 36333

Qy    1384 aaaactacatgaaaccctccgtacccatactcgcctggtaagcctatttaataccaccct 1443
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Qy    1444 cactgggctccatgaggtctcggcccaaaaccctactaactgttggatatgcctcccct 1503
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Db   36394 CACTGGGCTCCATGAGGTCTCGGCCCAAAACCCTACTAACTGTTGGATATGCCTCCCCCT 36453

Qy    1504 gaacttcaggccatatgtttcaatccctgtacctgaacaatggaacaacttcagcacaga 1563
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Db   36454 GAACTTCAGGCCATATGTTTCAATCCCTGTACCTGAACAATGGAACAACTTCAGCACAGA 36513

Qy    1564 aataaacaccacttccgttttagtaggacctcttgtttccaatctggaaataacccatac 1623
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Db   36514 AATAAACACCACTTCCGTTTTAGTAGGACCTCTTGTTTCCAATCTGGAAATAACCCATAC 36573

Qy    1624 ctcaaacctcacctgtgtaaaatttagcaatactacatacacaaccaactcccaatgcat 1683
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Db   36574 CTCAAACCTCACCTGTGTAAAATTTAGCAATACTACATACACAACCAACTCCCAATGCAT 36633

Qy    1684 caggtgggtaactcctcccacacaaatagtctgcctaccctcaggaatatttttttgtctg 1743
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Qy    1744 tggtacctcagcctatcgttgtttgaatggctcttcagaatctatgtgcttcctctcatt 1803
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Qy    1804 cttagtgccccctatgaccatctacactgaacaagatttatacagttatgtcatatctaa 1863
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Db   36754 CTTAGTGCCCCCTATGACCATCTACACTGAACAAGATTTATACAGTTATGTCATATCTAA 36813

Qy    1864 gccccgcaacaaaagagtacccattcttcctttttgttataggagcaggagtgctaggtgc 1923
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Qy    1924 actaggtactggcattggcggtatcacaacctctactcagttctactacaaactatctca 1983
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Db   36874 ACTAGGTACTGGCATTGGCGGTATCACAACCTCTACTCAGTTCTACTACAAACTATCTCA 36933

Qy    1984 agaactaaatggggacatggaacgggtcgccgactccctggtcaccttgcaagatcaact 2043
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Qy    2044 taactccctagcagcagtagtccttcaaaatcgaagagctttagacttgctaaccgctga 2103
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Qy    2104 aagaggggggaacctgtttatttttaggggaagaatgctgttattatgttaatcaatccgg 2163
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Db   37054 AAGAGGGGGAACCTGTTTATTTTTAGGGGAAGAATGCTGTTATTATGTTAATCAATCCGG 37113

Qy    2164 aatcgtcactgagaaagttaaagaaattcgagatcgaatacaacgtagagcagaggagct 2223
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Db   37114 AATCGTCACTGAGAAAGTTAAAGAAATTCGAGATCGAATACAACGTAGAGCAGAGGAGCT 37173

Qy    2224 tcgaaacactggaccctggggcctcctcagccaatggatgccctggattctccccttctt 2283
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Db   37174 TCGAAACACTGGACCCTGGGGCCTCCTCAGCCAATGGATGCCCTGGATTCTCCCCTTCTT 37233

Qy    2284 aggacctctagcagctataatattgctactcctctttggaccctgtatctttaacctcct 2343
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Db   37234 AGGACCTCTAGCAGCTATAATATTGCTACTCCTCTTTGGACCCTGTATCTTTAACCTCCT 37293

Qy    2344 tgttaactttgtctcttccagaatcgaagctgtaaaactacaaatggagcccaagatgca 2403
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Qy    2524 caattcagcaggaagcagttagagcggtc-tcggccaacctccccaacagcacttaggtt 2582
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Qy    2583 ttcctgttgagatgggg 2599
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Db   37534 TTCCTGTTGAGATGGGG 37550
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